

Dockets Management Branch (HFA-305)

Docket No. 98N-1265

Food and Drug Administration

5600 Fishers Lane

Rockville, MD. 20857

APR 20 10 40

I OPPOSE THE DRAFT M.O.U. being proposed by the FDA. In particular, I OBJECT to the definition of "inordinate amount" which restricts the availability and the right to obtain medically necessary compounded medications by limiting the number of prescriptions that can be shipped across state lines from specialized compounding pharmacies.

Margarete A. Fox  
Signature

4/16/99  
Date

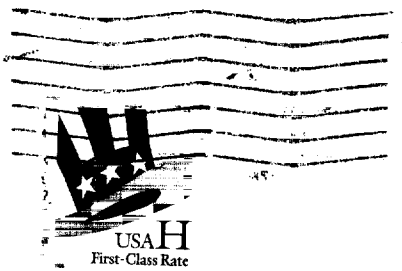
- Please do not restrict the ability of specialized pharmacies to send compounded prescription medications across state lines. I am a 65 yr. old woman who is menopausal and has been described as being "this close" to osteoporosis. I was advised to get on an HRT program and did try Premarin in patch form + cream form. But each time within weeks I had a greenish/yellow vaginal discharge and other symptoms that worried me. After testing my hormone levels, a different doctor, in Massena, N.Y., prescribed estrogen capsules and progesterone cream which I received from an out of state pharmacy. I have experienced no noticeable unwanted side effects, no ugly discharge, no monthly bleeding, but improved clearness of thinking and no vaginal dryness. Plus - the bone density exam I had in 1997 showed a 5% increase in bone density!! These individually compounded medications work.
- What does the term "inordinate amount" mean in the MOU? Why is it to apply to specialized compounding pharmacies that give a very real service to individual physicians and patients and not to the large drug companies?
- Respect the intelligence of the people in our country to know if our individual health is improved or made worse by the "one size fits all" philosophy of the large pharmaceutical companies. And
- respect the wisdom and professional concern of the doctors who treat the individual and are able at this time to contact specialized pharmacies and prescribe individually compounded medicines, even if these pharmacies are out of state.
- Please, do not take away our right to use doctor prescribed compounded medicines based on our individual health needs.
- Thank you for your concerned attention to this important matter.

Please fold, seal, and mail by March 22

98N-1265

Sincerely, C1234  
Margarete A. Fox

Margarete A. Fox  
2689 CR 21  
Canton, N.Y. 13617



**DOCKETS MANAGEMENT BRANCH (HFA-305)**  
**DOCKET NO. 98N-1265**  
**FOOD AND DRUG ADMINISTRATION**  
**5600 FISHERS LANE**  
**ROCKVILLE, MD. 20857**